

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

REMARKS

Claims 1-11 are pending in the present application. Claims 1-3, 7 and 8 are rejected. Claims 1-11 are herein amended. Applicant's representative thanks the Examiner for the courtesies extended in the telephone interview of January 23, 2007. Applicant's formal response to the comments contained in the Interview Summary is incorporated herein.

Applicant's Response to Objections to the Specification

The Office Action objects to the specification for several reasons. First, the Office Action notes that the specification contains an embedded hyperlink, which is not permitted under MPEP §608.01. This hyperlink is found in the specification at page 3, lines 11-12. Accordingly, Applicant herein amends the specification to remove this hyperlink. Applicant respectfully requests that this objection be withdrawn.

Next, the Office Action states that the specification does not contain an abstract of the disclosure. As discussed in the personal interview of January 23, 2007, the application was filed with an abstract, and the abstract appears in the electronic file wrapper on the U.S.P.T.O.'s Patent Application Information Retrieval (PAIR) system. Applicant respectfully requests that this objection be withdrawn.

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

Finally, the Office Action states that the title of the invention is not descriptive, and requires a new title. In response, Applicant herein amends the title as follows:

A METHOD AND APPARATUS FOR SEPARATING AND PURIFYING BIOPOLYMERS NUCLEIC ACIDS AND/OR PROTEINS USING ELECTROPHORESIS

Accordingly, Applicant respectfully requests that the objection to the title be withdrawn.

Applicant's Response to Claim Objections

Claims 3 and 8 were objected to under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Office Action states that claims 3 and 8 recite a “very small pillar array” and “a porous filter,” both of which are not gels, as being a gel. Thus, the Office Action states that claims 3 and 8 effectively expand the scope of claims 1 and 7, instead of limiting their scope.

In response, with regard to the first embodiment, Applicant herein amends claim 1 in order to recite “a partition” which may be a gel, a pillar array or a porous filter. With regard to the second and third embodiments, Applicant herein amends independent claims 2 and 7 to broadly recite “a partition.” Applicant also herein amends dependent claims 3 and 8 to more specifically recite that the partition is a gel, pillar array or porous filter.

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

Applicant's Response to Claim Rejections under 35 U.S.C. §112

Claims 1-3, 7 and 8 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that claims 1-3, 7 and 8 are confusing as to what the metes and bounds of a “gel” are. In response, as discussed above, Applicant herein amends claim 1 to recite “a partition” which may be a gel, pillar array or porous filter. Further, Applicant herein amends independent claims 2 and 7 to broadly recite a partition, and dependent claims 3 and 8 to more specifically recite that the partition may be a gel, pillar array or porous filter.

Additionally, the Office Action notes that claim 3 (and presumably claim 8) is indefinite with respect to what the metes and bounds of “very small” are. In response, Applicant herein amends claims 3 and 8 to remove this relative language.

Claims 1-3, 7 and 8 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

It is the position of the Office Action that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed subject matter.

The Office Action points out that the claims are interpreted to encompass separation and purification of any biological polymer as long as it has a net negative charge, wherein said

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

biopolymer can have virtually any size or mass. The Office Action also notes a lack of examples, and states that “the specification is effectively silent as to how similar molecules are to be separated and purified when at least a portion of the population of molecules would co-migrate.”

The Office Action goes on to state that “[i]t appears that applicant is attempting to satisfy the written description requirement of 35 U.S.C. §112, first paragraph, through obviousness.” It is unclear what the Office Action means by this. However, Applicant notes that MPEP §2163 states that “[t]he description need only describe in detail that which is new or not conventional.... This is equally true whether the claimed invention is directed to a product or a process.” Further, MPEP §2163 states that:

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. (citations omitted)

Applicant respectfully submits that the invention as claimed in the amended claims is sufficiently described in the specification. In particular, the independent claims are improved by reciting that the biopolymers are nucleic acids and/or proteins, and by specifying size differences between the biomolecules. Figures 1-3 and the corresponding text sufficiently describe the three embodiments of the method of separation of biopolymers.

Additionally, it is noted that the Office Action states that “in the absence of convincing evidence to the contrary” the claims are rejected as failing to comply with the written description requirement. It appears that the Office Action is applying an inappropriate standard of law.

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

According to MPEP §2163.03, “there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed.” Accordingly, it is respectfully requested that the written description rejections based on 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 1-3, 7 and 8 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

It is the position of the Office Action that the claims contain subject matter that was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Office Action notes that no working examples are provided, despite the disclosure of Figures 1-3 and the associated text explaining these figures. Additionally, the Office Action comments on the unpredictability of the art. In support of this, the Office Action points to Roffler et al. (U.S. Patent No. 6,617,118), which discloses that the mobility of PEG-modified proteins in a type of gel electrophoresis is slower than expected. However, this statement in Roffler is only relevant to *measuring* the size of a PEG-modified protein. Since a PEG-modified protein is still mobile in a gel, albeit more slowly than expected, it is possible to *separate* a PEG-modified protein from other biopolymers according to the claimed method.

The Office Action also states that “[t]he mass and charge of nucleic acids that have the same A, T, C and G composition cannot be distinguished even though they have a different sequence or ordering of the nucleotide, and one may be related to a disease and one not.” Thus,

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

it is the position of the Office Action that two nucleic acid sequences having an identical size, but different sequences, cannot be separated. Accordingly, as discussed above, Applicant herein amend the claims to recite differing sizes between the target biopolymer and the other biopolymers.

The Office Action further states that the invention relates to the separation and purification of biological polymers no matter how close in size and charge they are. In response, Applicant respectfully submits that the separation of biopolymers depends on the sensitivity of the gel, pillar array or porous filter. Applicant submits that one having ordinary skill in the art would have known what type of partition is appropriate with respect to sensitivity when seeking to separate particular target biomolecules from particular other biomolecules.

Next, the Office Action notes that claim 2 recites the biopolymer being moved in three directions, interpreted as movement along three axes. In order to clarify claim 2, Applicant herein deletes this language. Additionally, Applicant herein amends claim 2 such that it is in independent form, since the method of operation is significantly different from that of the embodiment of claim 1.

The Office Action states that the claims encompass preservation of the biopolymers for an indefinite period of time, and that the specification does not set forth reaction conditions and starting materials needed to practice the invention. In response, Applicant respectfully submits that such reaction conditions and starting materials would have been known to one having ordinary skill in the art.

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

Finally, Applicant notes that the claims are amended into include extensive revisions in order to improve their clarity and form. Accordingly, Applicant respectfully requests that all rejections based on 35 U.S.C. §112, first and second paragraphs, be withdrawn.

Applicant's Response to Claim Rejections under 35 U.S.C. §102

Claims 1-3, 7 and 8 were rejected under 35 U.S.C. §102 as being anticipated by Wijangco et al. (U.S. Patent No. 4,863,582).

It is the position of the Office Action that Wijangco discloses the invention as claimed. Wijangco is directed at a process and apparatus for purifying and concentrating DNA. The apparatus utilizes a lysate container 46, a gel matrix retainer 50, a dialysis membrane 56 and electrodes 42 and 44.

The method of using the apparatus in Wijangco is described at column 7, line 25 to column 8, line 18. Briefly, the method includes four cycles: RUN, RINSE1, RINSE2, and ELUTE. The RUN cycle includes loading a lysate containing DNA into a lysate chamber along with a run buffer solution. An electric field is generated, causing the lysate to migrate into the gel. A circulation pump is also activated. After 2 ½ hours, the electric field and pump are deactivated, and the buffer solution is removed.

Next, the RINSE1 cycle begins by introducing a rinse buffer into the chamber. The circulation pump and electric field are reactivated. The system runs for 40 minutes, then the pump and electric field are deactivated. The Rinse buffer is removed. Then, the RINSE2 cycle, which is identical to the RINSE1 cycle, begins.

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

Finally, the ELUTE cycle begins. At this time, DNA remains in the gel, while other contaminants have been removed. A Rinse buffer is introduced into the chamber, and the electric field and pump are reactivated. DNA then runs from the gel into the dialysis membrane, and the rinse buffer is removed. The DNA may then be collected from the dialysis membrane.

Thus, in the apparatus and method of Wijangco, only a single solution is present in the apparatus at a time. On the other hand, in the claimed method, there is a partitioning between a first and second solution, or between a first, second and third solution. Further, biopolymers are moved from one solution to another. Wijangco does not disclose such partitioning or movement, since only one solution (run buffer or rinse buffer) is present at any given time. Additionally, Wijangco does not disclose or suggest the use of magnetophoresis, as recited by claim 7. Therefore, for at least the above reasons, since Wijangco does not disclose all recited features, it cannot anticipate claims 1, 2 and 7. Applicant respectfully traverses the rejection.

With respect to claim 1, in the interview, the Examiner raised additional issues regarding the first embodiment, illustrated in Figure 1. Specifically, the Examiner stated that the method of claim 1 could be anticipated by the use of a traditional electrophoresis system, wherein the sample was permitted to run off a gel, into a solution. In response, Applicant respectfully notes that claim 1 also recites the additional step of “separating said target biopolymer from said second solution.” The present invention is proposed on the assumption that it is applied to a DNA inspecting device such as that described in Tanaami (U.S. Patent Application Publication No. 2004/0137607). Biopolymers separated by the present invention are sent to a detection step, which is a next step. In order to apply a device for separating biopolymers to micro/miniatuerized

Amendment
Serial No. 10/801,544
Attorney Docket No. 042187

total analysis systems (μ TAS), it is necessary to precisely manage an amount of biopolymer to be separated and a time required for separating biopolymers. According to the present invention, it is possible to easily set and manage the amount of biopolymers by determining a sectional area of a flow channel or a width of a gel. Favorable reconsideration is respectfully requested.

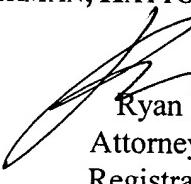
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicant would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicant's undersigned attorney.

If this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp/mra